



Joint meeting of CVO/CMO/HSC on Influenza Preparedness in the context of One Health

The EU Joint Procurement mechanism - example of pandemic influenza vaccines

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What is it?

A **voluntary mechanism** enabling participating Member States to purchase jointly medical countermeasures for serious cross-border threats to health

Aim :

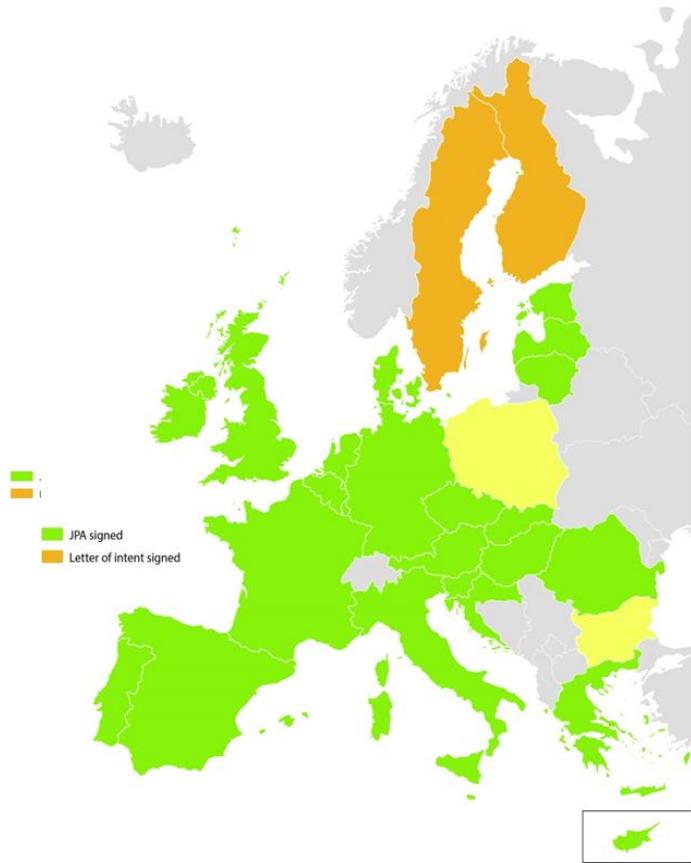
- **Improving Member States' preparedness to mitigate serious cross-border threats to health**
- **Ensuring more equitable access to specific medical countermeasures**
- **Ensuring more balanced prices**



Joint Procurement Agreement

A Joint Procurement Agreement was **adopted by the Commission 10 April 2014** to implement Article 5 of Decision 1082/2013/EU.

So far **24 EU Member States signed the Agreement**





Towards the establishment of the Mechanism

- **Lessons learned from the last influenza pandemic in 2009:**
 - the 2010 "Assessment report on EU-wide Pandemic Vaccine Strategies" and the Belgian Presidency "Conference on lessons learned from the A(H1N1) pandemic" **identified weaknesses related to price, liability and availability of vaccines.**
 - many EU Member States struggled to obtain sufficient quantities of vaccines as quickly as needed and had to accept unfavourable contractual terms
- **The Health Ministers at the Council of December 2010 invited the Commission to develop a joint procurement mechanism for pandemic vaccines.**



The Joint Procurement Mechanism

- **Decision 1082/2013/EU on serious cross-border threats** to health **provided the legal basis** for the establishment of the joint mechanism.
- **Article 5 of that Decision** provides:
"The institutions of the Union and any Member States which so desire may engage in a joint procurement procedure [...] with a view to the advance purchase of medical countermeasures for serious cross-border threats to health."



The Joint Procurement Agreement

- It is a **framework laying down common rules** for practical organisation of joint procurement procedures with a view to advance purchase of medical countermeasures.
- All **decisions** in the framework of the Joint Procurement Mechanism **are taken by the Member States through the Steering Committees**.



What are serious cross-border threats to health?

- A '**serious cross-border threat to health**' is a life-threatening or otherwise **serious hazard to health of biological, chemical, environmental or unknown origin**, which spreads or entails a significant risk of spreading across the national borders of Member States, and which may necessitate coordination at Union level in order to ensure a high level of human health protection.
- These could include **communicable diseases, biotoxins, chemical and environmental events**.



What countermeasures can be jointly procured?

- Diagnostic kits and services - laboratory services
- Medication; vaccines - antivirals - treatments...
- Medical devices
- Other goods and services; decontamination kits, masks and protective equipments...



What is the expected added value?

- Better **preparedness** for outbreaks by having reservation contracts or purchasing contracts in place before outbreaks occur;
- Strengthened purchasing power gained by pooling needs and increasing the volumes to be procured, resulting in **better purchasing conditions**;
- Greater exchange of best practices and **pooling of expertise** between Member States;
- **Equal treatment** of Member States participating in a procurement procedure;



Ongoing and future procedures

- First procurement procedure for **Botulinum anti-toxin**, was successfully concluded in 2016.
- **Pandemic influenza vaccines: 19 Member States and the Commission are currently working together with a view to advance purchase of pandemic influenza vaccines.**
- Future procedures: MS have expressed interest for further Joint Procurement Procedures for **diphtheria anti-toxin**, **Tuberculin** and **BCG vaccines**.



Joint procurement of Pandemic Influenza Vaccines (PIV)

The **last** pandemic influenza was in 2009, other influenza **pandemics** happened in 1968, 1957, 1918.

- **1918 Pandemic (H1N1 virus):** *the most severe pandemic in recent history. About 500 million people became infected and at least 50 million deaths.*
- **1957-1958 Pandemic (H2N2 virus):** "Asian Flu", *1.1 million deaths.*
- **1968 Pandemic (H3N2 virus):** *1 million deaths*
- **2009 H1N1 Pandemic (H1N1pdm09 virus):** *This new H1N1 virus contained a unique combination of influenza genes not previously identified in animals or people.*



Joint procurement of Pandemic Influenza Vaccines (PIV)

- The average time of the **inter-epidemic periods** between pandemic influenza outbreaks **cannot be predicted at all.**
- That is why EU MS decided to join forces to be better prepared.
- Preparations for the **joint procurement of pandemic vaccines are in an advanced stage.**
- **Signature of the contract** is planned for the first quarter of 2018.



Joint procurement of Pandemic Influenza Vaccines (PIV)

Subject of the contract: purchase and supply of PIV to 35 Contracting Authorities from 19 MS and the Commission in the event of an influenza pandemic.

The contractor shall:

- Hold a valid EU marketing authorisation for pandemic preparedness vaccine
- Ensure the production capacity is maintained for the duration of the contract
- Submit its application for modification of marketing authorisation, following declaration of a pandemic by WHO and 3 months after receipt of virus strain from WHO reference laboratory



See more at

http://ec.europa.eu/health/preparedness_response/docs/jpa_implementation_article7_en.pdf

Thank you for your attention